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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/058,069	01/29/2002	Gary R. Braslawsky	0280727 2001-30-0080CP1	2502

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EXAMINER	
BLANCHARD, DAVID J	

ART UNIT	PAPER NUMBER
1643	

DATE MAILED: 07/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action Before the Filing of an Appeal Brief	**Application No.** 10/058,069	**Applicant(s)** BRASLAWSKY ET AL.	
	Examiner David J. Blanchard	**Art Unit** 1643	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 06 July 2006 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☒ The period for reply expires 3 + 2 months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: *20,29,38-40,55,62,63,68,75-81 and 84-100*.
   Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). _____
13. ☐ Other: _____.

Continuation of 11. does NOT place the application in condition for allowance because: The rejection of claims 20,29,38-40,55,62,63,68,75-81, 84-92 and applied to newly added claims 93-100 under 35 U.S.C. 103(a) as being unpatentable over Gillies et al (Human Antibodies and Hybridomas, 1(1):47-54, 1990, cited previously) as evidenced by the specification in view of Kashmiri et al (WO 00/26394, 5/11/00) and Anderson et al (U.S. Patent 6,348,581 B1, priority at least to 2/18/1998, cited previously) and Thorpe et al (U.S. Patent 6,342,219 B1, 4/28/1999, cited previously) is maintained.

The response filed 7/6/2006 reiterates that Gillies et al does not describe or even suggest the possibility of the existence of dimeric, tetravalent, CH2 domain deleted anti-TAG72 antibodies of the claimed invention and none of the cited secondary references describe or suggest making or using the claimed dimeric, tetravalent, CH2 domain deleted anti-TAG72 antibodies which are substantially purified. Applicant states that prior to their discovery and purification of dimeric, tetravalent, CH2 domain-deleted antibodies it was not known that such antibody complexes existed. This has been fully considered but is not found persuasive. While it is true that Gillies et al do not specfiically teach or suggest the possibility of the existence of dimeric, tetravalent, CH2 domain-deleted anti-TAG72 antibodies, as discussed in the previous office action, one of ordinary skill in the art at the time the inevnion was made would have been motivated and had a reasonable expectation of success to modify the CH2 domain deleted mouse anti-TAG72 antibody (B72.3) of Gillies et al in which the CH3 domain is fused directly to the hinge region with the humanized anti-TAG72 CC49 VH and VL sequences taught by Kashmiri et al to reduce the immunogenicity of the CH2 domain deleted antibody and enhance the therapeutic index of the CH2 domain deleted antibody as a targeting element for delivering various cytotoxic agents for human cancer therapy as taught by Anderson et al and Thorpe et al. Therefore, the CH2 domain deleted anti-TAG72 CC49 antibody comprising the humanized heavy and light chain variable region sequences of SEQ ID Nos:7 and 9, respectively, wherein the CH3 domain is fused directly to the hinge region of the prior art is identical to the claimed CH2 domain deleted anti-TAG72 CC49 antibody and the CH2 domain deleted anti-TAG72 CC49 antibody of the prior art would necessarily non-covalently associate into a tetravalent dimeric CH2 domain deleted anti-TAG72 CC49 antibody. Applicant is reminded that products of identical chemical composition cannot have mutually exclusive properties. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. In re Spada 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). See MPEP 2112.01. Thus, the properties with which applciant argues would necessarily flow from the teachings of the prior art. Where the claimed and prior art products are identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of obviousness has been established. In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). Further, while it was not known that dimeric, tetravalent, CH2 domain deleted anti-TAG72 antibodies existed, "[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." Atlas Powder Co. v. Ireco Inc., 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). See MPEP 2112.

With respect to the dimeric, tetravalent, CH2 domain deleted anti-TAG72 antibodies being substantailly purified, the cited references teach antibody purification using standard procedures in the art including those disclosed in the present application. For example, Kashmiri et al teach purification of the CC49 antibodies "according to standard procedures in the art" to at least about 90-95% homogeneity or more preferably 98-99% or more homogeneity (pg. 17, lines 20-24) and Thorpe et al teach antibody pruification using the techniques disclosed in the present application, i.e., protein G and HPLC columns (e.g., Thorpe at col. 61, lines 10-19). Thus, the desireability of purifying the humanized CC49 CH2 domain-deleted antibodies as taught by Gillies et al and Kashmiri et al and Anderson et al and Thorpe et al, is made explicit in the references, particularly for therapeutic purposes in cancer patients, and in view of the well-known and standard purification techniques in the art that are similar to the disclosed methods for purifying the humanized CC49 CH2 domain-deleted antibodies, the presently claimed form of the humanized CC49 CH2 domain-deleted antibodies would have been prima facie obvious to one of ordinary skill in the art.

Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references and the rejections is maintained.

Respectfully,
David J. Blanchard
571-272-0827

SHEELA HUFF
PRIMARY EXAMINER